

## **REMARKS**

### **I. Background**

The present Amendment filed concurrently with the Request for Continued Examination (RCE) is in response to the Final Office Action mailed March 23, 2007. Claims 1-3, 6, and 7 were pending in the application for consideration at the time of the mailing of the Office Action. Claims 1-3 and 6-7 are currently cancelled, and new claims 8-11 have been added. Thus, claims 8-11 are currently pending for consideration on the merits.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

### **II. Proposed Claim Amendments**

The new claims 8-11 have been added to replace claims 1-3, 6, and 7 in order to more clearly recite the present invention. As such, new claims 8-11 are fully supported by claims 1-3, and 6 as pending prior to the Final Office Action, and do not include any new matter. Thus, Applicant respectfully submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

### **III. Rejections Under 35 U.S.C. § 103(a)**

The Office Action rejects claims 1-3, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over *Struszczyk et al.* (WO01-87988). Applicant respectfully traverses the rejection because the Office Action has not established a *prima facie* case of obviousness with regard to the presently pending claims 8-11.

Applicant respectfully asserts that *Struszczyk* does not teach or suggest each and every claim element recited in the presently pending claims. *Struszczyk* is completely devoid of teaching or suggesting a **“method for removing protein from a chitosan composition,”** or providing any reason or suggestion for modifying the teachings thereof to obtain such a method as presently claimed. In fact, *Struszczyk* is devoid of teaching or suggesting that any of the chitosan compositions disclosed therein contain any protein, or any desirability or benefit for having protein removed from a chitosan composition. As such, *Struszczyk* does not teach or suggest **“providing an acidic aqueous composition containing chitosan at  $\geq 0.001\%$  by weight and dissolved protein at  $\geq 0.001\%$  by weight.”** Since *Struszczyk* is devoid of teaching or suggesting a chitosan-containing composition that also includes **protein at  $\geq 0.001\%$  by weight**, there is no teaching or suggestion for **“precipitating microcrystalline chitosan from the aqueous composition having the dissolved protein.”** Additionally, *Struszczyk* does not teach or suggest **“separating said precipitated microcrystalline chitosan from the aqueous composition having the dissolved protein to obtain a microcrystalline chitosan composition having protein at  $\leq 10$  ppm.”** Thus, *Struszczyk* does not teach or suggest each and every element of the presently claimed invention.

Applicant respectfully asserts that the presently claimed invention is not inherent in the teachings of *Struszczyk*. The principles of inherency recited in the Office Action are not applicable to the instant claims because the presently claimed invention is drawn to a method of making a product, and **not** to a device that can be used in performing a method or to a method of using a device. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by *probabilities or possibilities*. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” (See M.P.E.P. §2112 citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)). “[A] basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art” must be proved (*Id.* citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). In *Struszczyk* there is no indication that the starting chitosan compositions include any protein, and there is no extrinsic evidence that the starting chitosan compositions necessarily

include proteins, especially in the amount recited in the claims. In fact, the examples of *Struszczyk* utilize a highly purified commercially available chitosan product (Primex Chitoclear). Thus, it is not inherent for the starting chitosan compositions that are formed into microcrystalline chitosan with the methods of *Struszczyk* to include proteins in the amount recited in the claim, and therefore, the presently claimed invention is not inherent under the methods of *Struszczyk*.

The presently pending claims recite claim elements involving proteins that are **not recited or inherent** in *Struszczyk*, as discussed above, and there is no reasonable interpretation of *Struszczyk* that would result in such claim elements being inherent. Since *Struszczyk* does not teach or suggest each and every element of the presently claimed invention, and does not provide any motivation or suggestion for a “**method for removing protein from a chitosan composition**,” a *prima facie* case of obviousness has not been established. Thus, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103(a), and requests allowance of claims 8-11.

### **SUMMARY**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as the required motivation or suggestion to combine the relied upon notice with the other art of record.

Applicant believes claims 8-11 are in allowable form as discussed above. Thus, Applicant respectfully requests reconsideration of the application and allowance of presently pending claims.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney by telephone at (801) 533-9800.

Dated this 14<sup>th</sup> day of June, 2007.

Respectfully submitted,

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